Evaluating Cannabidiol (CBD) to Enhance the Analgesic Effect of Hydromorphone in Humans

NCT: 04036968

Informed Consent Date: November 1, 2021

If appropriate for this study, a scanned copy of the signed consent form should be uploaded to the participant's Epic/EMR record.

Patient I.D. plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: Enhancing Medication-based Analgesia in Humans- Study 2

Application No.: IRB00214289

Sponsor/Supporter/Funded By: National Institute on Drug Abuse

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You are being asked to join a research study. Participation in this study is voluntary. Even if you decide to join now, you can change your mind later.

1. Research Summary (Key Information):

The information in this section is intended to be an introduction to the study only. Complete details of the study are listed in the sections below. If you are considering participation in the study, the entire document should be discussed with you before you make your final decision. You can ask questions about the study now and at any time in the future.

This research is being done to evaluate whether combining two medications is an effective way to treat pain.

The study consists of an eligibility Screening period and 5 study sessions that are scheduled approximately 1 week apart. Each study session will last an entire day (around 8 hours). At the beginning of each study session you will receive 2 blinded study medications. The medications are all FDA-approved medications but are being given for non-FDA approved reasons as part of this study and may be from any of the following categories: a prescription stimulant, a prescription cannabinoid (related to the active ingredient in cannabis or marijuana), a benzodiazepine (e.g., anti-anxiety medication), an opioid (e.g., a pain medication), an over-the-counter medication, or a placebo (contains no medication, like a sugar pill). Neither you nor the staff member will know what combination of medications you have received.

Throughout each session, we will collect information about how the study medications make you feel and whether they help reduce pain. We will measure their ability to reduce pain by conducting some pain testing procedures with you in our laboratory. These procedures are commonly used by laboratories throughout the world and include the application of a topical cream and we describe them in more detail for you later in this form.

If you decide to participate in this study, the main risks will be related to taking the study medications and the pain testing procedure. Even though you won't know exactly what medications you are receiving, we describe the effects you might experience in detail for you later in this form so that you can make an informed decision about whether you want to participate. Some risks could be serious. In addition, even though the pain testing procedure may produce some level of pain, we expect the pain to be relatively mild, and you will be in charge of how much pain you experience because you can chose to end the procedure at any time (with no study-related consequences).

You can decide to participate now and change your mind later with no consequences.

There will be no personal benefit to you from study participation, but your participation, and the knowledge gained, may benefit others in the future.

2. Why is this research being done?

This research is being done to evaluate whether combining two medications is an effective way to treat pain.

Are there any investigational drugs/devices/procedures?

This study will provide you with two medications to swallow at the beginning of every study session. All the medications that are being administered in this study are approved by the U.S. Food and Drug Administration (FDA), however their use in this study is investigational because we are using them in a way that the FDA has not yet approved. The FDA is allowing the use of these study medications for this study.

The medications that may be tested in this study include prescription stimulants, prescription cannabinoids (related to the active ingredient in cannabis or marijuana), benzodiazepines (e.g., anti-anxiety medication), prescription opioids (e.g., a pain medication), over-the-counter medications, or placebo (contains no medication, like a sugar pill).

Who can join this study?

People with who are between 18 years and 75 years old and healthy may join this study.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

Study Screening:

The goal of the study Screening is to make sure that you are eligible for the study and healthy, so that participating in this study will not put you at risk. Part of this Screening process may be conducted remotely.

As part of your Screening, we will ask you a series of questions and will collect a blood sample (no more than 2 tablespoons) and urine sample from you to ensure it is safe for you to be enrolled into the study and to help us understand your response to the study medications. You will also complete an electrocardiogram (ECG) to make sure your heart is healthy.

Prior to beginning your 1st study session (see below) you will also meet with a medical staff member to complete a brief history and physical.

Study Sessions:

If you are determined to be eligible after completing our study Screening visit then you will be asked to complete 5 study sessions. Each session will last all day (around 8 hours). You are welcome to spend the night before each session in our clinical research unit, which is located on our same hospital campus. If you prefer not to spend the night, you may arrive the morning of the session. However, since we cannot be sure how you will feel after taking the study medications, we will ask you to not drive to the sessions and will pay for a taxi to bring you to and from the sessions if needed.

Before we begin each session, we will collect a urine sample that will be tested for recent drug use. If you are female, we will also test you for pregnancy and will collect a blood sample (no more than 2 tablespoons) from you that we will test to determine your hormone status. It is possible that the staff member may cancel your study session if your urine results indicate recent drug use or pregnancy. If your study session is canceled, you will not receive payment for that visit and will have to reschedule your session for another day.

We will work with you to ensure you have a calorie-controlled breakfast prior to your session beginning. Study sessions are expected to last all day. During the session you will first be asked to complete some questionnaires that ask you about how you feel and to complete some pain testing procedures (these are described in more detail below). You will then receive a capsule and an oral liquid. These contain different study medications for you to swallow. The medications you receive may contain a prescription stimulant, a prescription cannabinoid (related to the active ingredient in cannabis or marijuana), a benzodiazepine (e.g., anti-anxiety medication), an opioid (e.g., a pain medication), an over-the-counter medication, or a placebo (contains no medication, like a sugar pill). Neither you nor the staff member will know what combination of medications you have received. However, in the case of an emergency, a study doctor can quickly find out what medications you received.

After you receive the study medications, we will ask you to continue completing questionnaires, computerized tasks, and pain testing procedures at regular intervals throughout the session day. We will also collect information about how your body is responding to the study medications, by collecting your blood pressure, heart rate, pupil diameter, and other measures of biological response. At the end of the session, we will provide you with a taxi ride home. The morning after a session, we will send you a secure web link that you can use to complete a final set of questions related to the session. This link will include only a small number of items that you answered with us during the session. We are collecting this information to make sure we have completely captured everything about how the study medications made you feel.

You will be asked to complete 5 of these study sessions. Each session will be identical and we ask you to complete them about 1 week apart.

Pain Testing Procedures:

We will ask you to complete some pain testing procedures as part of this study. These tests help us to understand whether combining medications can reduce pain, and these data will help us learn whether there are new and better ways for the medical community to be treating pain in their patients.

We will be using well-validated pain-testing procedures that are used by several other laboratories throughout the world. Some of the pain testing will include the application of a topical cream.

It is important that you know that even though each procedure may produce some level of pain, we expect the pain to be relatively mild, and you will be able to end the procedure at any time (with no study-related consequences).

We are conducting several different pain procedures because they all activate different pain pathways, however the pain they produce is brief and none of these procedures are expected to produce any lasting pain or damage to you. Specifically, you will be asked to place your arm and/or hand into cold water. This may be mildly painful, however you will be able to remove your arm/hand whenever you want. A staff member will also place a small device on some of your muscles, which will make you feel some pressure on those muscles. This procedure may also be mildly painful, and you will be able to end the procedure whenever you wish. We will also tap a place on your hand or elsewhere with some pencil-like objects. These may also be mildly painful, but again you will be able to stop the task whenever you want. Finally, we rub a cream on your hand that contains capsaicin, which is the chemical that makes some peppers hot. We will then use a machine that generates heat to evaluate your response to temperature-induced pain. A staff member will introduce you to these procedures during the Screening visit so you will be able to make an informed decision about whether you'd like to participate in this study.

4. What happens to data and biospecimens that are collected in the study?

Johns Hopkins and our research partners work to advance science and public health. The data and biospecimens we collect from you are important to this effort.

Biospecimens may include any of the following: blood, tissue, saliva, urine, bone marrow, cells, etc. Most biospecimens contain DNA, which is the genetic code for each person.

If you join this study, you will not own the data and/or biospecimens collected from you as part of this research study. If researchers use them to create a new product or idea, including those that may have commercial value, you will not benefit financially from these efforts.

What testing or procedures may be done with your biospecimens?

Your biospecimens may be used for a variety of research purposes. The specific testing that will be part of this study includes testing for drugs of abuse, pregnancy, and general medical health. At the beginning of each study session, we will also collect a blood sample from women that we will use to analyze their hormone levels, because there is reason to believe that female hormones may change a woman's response to the study medications.

We would also like to collect an optional genetic sample from all study participants. This will be collected as a saliva sample and will be stored for future genetic testing. The goal of this sample will be to help us learn more about whether genetics impacts response to different FDA-approved medications. *This sample is optional and your decision about whether to provide the sample will not impact your eligibility for the study.* If you decide to provide us with a genetic sample, you should know that the Genetic Information Nondiscrimination Act (GINA) is a federal law that helps reduce the risk of discrimination by health insurers or employers based on your genetic information. GINA does not protect you from discrimination if you apply for other types of insurance (such as life, disability or long-term care). GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

Genetic information is unique to you and your family. Even without your name or other identifiers, it may be possible to identify you or other members of your family with your genetic information. Johns Hopkins follows procedures so that people who work with your DNA information for research cannot discover it belongs to you, unless you have given consent. However, new techniques may be developed that in the future make it easier to link your genetic data to you, so we cannot promise that your genetic information will never be linked to you.

How will your data and/or biospecimens be shared now and in the future?

Sharing data and/or biospecimens is part of research and may increase what we can learn from this study.

Often, data/biospecimen sharing is required as a condition of funding or for publishing study results. It also is needed to allow other researchers to validate study findings and to come up with new ideas.

Your data and/or biospecimens may be shared:

- directly with research collaborators, other researchers, sponsors, government agencies, publishers of papers and other research partners
- through government or other databases/repositories

Data/biospecimen sharing could change over time, and may continue after the study ends.

We will do our best to protect and maintain your data/biospecimens in a safe way. Generally, if we share your data/biospecimens without identifiers (such as your name, address, date of birth) further review and approval by an IRB is not needed. However, when we share data/biospecimens, we limit the uses of the information and whether these data/biospecimens can be shared with another research team. If data/biospecimens are shared with identifiers, further IRB review and approval may be needed and the IRB will determine whether additional consent is required.

Johns Hopkins researchers may also use the biospecimens collected in this study for future research purposes, which may include gene sequencing and genetic testing. Each cell contains your complete DNA. Gene sequencing of your DNA provides researchers with the code to your genetic material. This future research may be unrelated to the current study and may include outside collaborators. Because science constantly advances, we do not yet know what future testing may include. If biospecimens are tested/used in ways not described above, further IRB review and approval may be needed and the IRB will determine whether additional consent is required.

If you are not comfortable with the use of your data/biospecimens in future research, you may not want to participate in this study. However, you can decline the collection and storage of the genetic biospecimen for future research.

Will you allow us to store and use the genetic biospecimens we collect for this study for future research?

YES ☐ _____
Signature of Participant

NO ☐ _____
Signature of Participant

5. What are the risks or discomforts of the study?

Study Drugs:
The largest risk of this study is associated with the medications you will receive. Side effects of the medications you will be receiving are expected to be mild and short-lived. You will be screened before enrolling in the study to ensure you are at a low risk of experiencing any study medication-related side effects.

It is important that you understand the potential side effects that you could experience from the study medications. These medications have been administered to people previously either as treatments for different medical illnesses or in other experimental studies. Below is a list of side effects that have been reported by some people who have taken these medications, however it is important to remember that some of these side effects may be related to the medical illnesses being treated and not a result of the medication itself. Side effects are also more likely to happen when the medications are taken for several days in a row, which is different from how you will be taking the medications in this study.

- Dermatologic: Rash (7-13%); Reddening of the face (2%), Itchy skin, 1-8%)
- Gastrointestinal: Constipation (7-31%), Nausea (9-28%), Decrease in Appetite (16-22%), Diarrhea (9-20%), Vomiting (6-14%)
- Cardiovascular: Low blood pressure (less than 2%), Fainting (less than 2%)
- Immunologic: Reoccurrence of viral, fungal or other infections (41%). The frequency of this side effect came from studies where subjects received the dose continuously for 14 weeks. It is unlikely that you will experience this effect with the same frequency due to the lower doses and infrequent administration in this study.
- Neurologic: Weakness or Dizziness (1-11%), Headache (1-12%), Sleepiness(2-25%), Coma (less than 2%), Jerking of muscles (less than 2%), Increased intracranial pressure (less than 2%), Difficulty Sleeping, Insomnia, or Sleep Disorder (% not specified)
- Psychiatric: Suicidal thoughts or behaviors (less than 2%)
- Respiratory: Brief stop in breathing (less than 1%), Stopping breathing (less than 2%), Not breathing enough oxygen(% not reported)
- Hepatic: Increased liver enzyme levels (8-16%)
- Other: Drug dependence/Addiction or Drug Withdrawal (less than 1%), Fatigue or Feeling generally unwell (% not reported)

It is important for you to know that, in extreme cases, these medications may cause your breathing to slow down or stop. They could also cause a severe allergic reaction or even death. You will undergo extensive medical testing during the Screening visits to determine whether you have any of the risk factors that would increase the likelihood that you would have an extreme reaction to the study medication and will not be enrolled into the study if we have any reason to believe that the study medication would put you at undue risk.

Risks from Combining the Study Medications:
Although there is no evidence that combining the study medications results in negative side effects, it is always possible there may be some interactions between these medications that are not yet known. We will carefully monitor emerging medical information about these drugs and will discontinue the study medications if new information indicates these medications should not be combined.

Pain Testing:
You will likely experience some discomfort from the pain testing procedures that are conducted during the study. The pain is expected to be mild and short-lived, and you will be able to end your participation in the pain sessions at any time.

Capsaicin:
Capsaicin is the main ingredient in hot peppers, and is used as an over-the-counter drug for the treatment of pain in products like Icy Hot. The dose of capsaicin we are using is higher than what is available over the counter, although it is less than half of the dose in a single habanera pepper. Capsaicin does cause some pain that is similar to how a hot pepper may feel when it is eaten. Capsaicin may produce some local redness and swelling that generally disappears within a day. The area of skin where the capsaicin is applied could be sensitive for up to 48 hours. Capsaicin may cause a burning feeling in the eyes or other areas of the body if accidentally rubbed onto other skin areas. We will take precautions to make sure this does not happen. We will limit the exposure area to a small square on the back of the hand and will wash the capsaicin off with alcohol after each session. If needed, we can use some ice to reduce any continued discomfort you may experience.

Blood Draw:
We will use a needle to draw blood from you. Taking blood may cause discomfort, bleeding, or bruising where the needle enters the body. In rare cases, it may result in fainting. There is a small risk of infection.

Legal Risks:
It is possible that your urine samples will test positive for medications that could be considered abusable by your employers or law enforcement professionals (e.g., stimulants, cannabinoids, opioids). If this is a concern to you then, with your permission, we can provide you with a letter that confirms your participation in the study and the potential for you to test positive for drugs that could be considered abusable for up to 7 days following a study session.

ECG:
An ECG will be conducted to determine that you heart is healthy enough for study participation. To conduct the ECG you will have electrodes placed on your chest, and you may find these cold or uncomfortable, though they are not expected to produce any pain. It is possible that the ECG may reveal abnormalities in your heart functioning that could be clinically significant. In these cases, the study medical team will inform you of the abnormalities and will provide you with relevant information you need to follow-up with your own doctor.

Interviews or questionnaires:
You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.

Confidentiality:
There is the risk that information about you may become known to people outside this study.

Unknown risk
There may be side effects and discomforts that are not yet known.

6. Are there risks related to pregnancy?

This research may hurt an embryo or fetus in ways we do not currently know. To protect against this risk, we will test all women for pregnancy before joining the study and prior to every study session. Any woman who is found to be pregnant will not receive study medication and will be discharged from the study.

It is unknown whether this research may hurt an embryo or fetus.

7. Are there benefits to being in the study?

There is no direct benefit to you from being in this study. However, your participation in the study will help us to learn more about how to better treat pain, and whether certain combinations of medications should be used for that purpose.

8. What are your options if you do not want to be in the study?

You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

9. Will it cost you anything to be in this study?

No.

You will receive a separate Insurance and Research Participant Financial Responsibility Information Sheet (Sheet). This Sheet will give you the following information:

- The procedures, tests, drugs or devices that are part of this research and that will be paid for by the study (no cost to you).
- The procedures, tests, drugs or devices that will be billed to you and/or your health insurer. If you have health insurance, you will be responsible for any co-pays or deductibles not covered by your insurance.

10. Will you be paid if you join this study?

You will be compensated up to $1300 for your time in the study, and your earnings are illustrated in this table. You will receive each session payment at the end of the session.

Visit	Payment
Screening	$50 (May be split into several payments)
Session 1	$150
Session 2	$200
Session 3	$250
Session 4	$300
Session 5	$350
Total	$1300

You may be required to provide your social security number to be paid for taking part in this study. Federal tax law requires that you report your research payments when you file your taxes. If your total payments from Johns Hopkins exceed $600 per year, Johns Hopkins will report these payments to the Internal Revenue Service and you will receive a 1099-MISC form from us

11. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, Johns Hopkins may use or share your health information that it has already collected if the information is needed for this study or any follow-up activities.

12. Why might we take you out of the study early?

You may be taken out of the study if:

- Staying in the study would be harmful.
- You need treatment not allowed in the study.
- You fail to follow instructions.
- You become pregnant.
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

13. How will your privacy be maintained and how will the confidentiality of your data be protected?

HIPAA Authorization for Disclosure of Protected Health Information

What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Johns Hopkins Medicine and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive, or use your private health information include the researchers and their staff who may be a part of Johns Hopkins Health System, Johns Hopkins University or the Johns Hopkins Applied Physics Laboratory. Additionally, we may share your information with other people at Johns Hopkins, for example if needed for your clinical care or study oversight. To improve coordination of your research and clinical care, some information about the study you join will be included in your electronic medical record.

By signing this form, you give permission to the research team to share your information with others outside of Johns Hopkins. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team.

We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

How will your information be protected?
This study will collect identifiable information (such as your name and date of birth). This information is necessary to ensure that we have enrolled you into the study properly. However the research team takes your confidentiality very seriously. We will collect only the minimal identifiable information necessary for this study. We will assign a unique study number to you that will be used on all of your study forms, and we will store any document that states your identifiable information in a separate physical location away from any study questionnaires so that your study number can not be immediately linked. Only staff members who are approved to work on this study and who have completed appropriate safety trainings will be permitted access to these forms. All of your information will be stored in study binders in locked rooms. Your data will be stored on computer files on encrypted and secure computers.

14. What is a Certificate of Confidentiality?

Your study information will also be protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

15. What treatment costs will be paid if you are injured in this study?

Johns Hopkins and the federal government do not have programs to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

By signing this form, you will not give up any rights you have to seek compensation for injury.

16. What other things should you know about this research study?

During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time. If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

During this study, you will not have access to certain medical information and test results collected for study purposes. If an emergency occurs while you are in the study, medical information needed for your treatment can be made available to your study doctor and other physicians who treat you. When the study is completed, all the information in your medical record will be available to you.

What is the Institutional Review Board (IRB) and how does it protect you?
This study has been reviewed by an Institutional Review Board (IRB), a group of people that reviews human research studies. The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study. You may contact the IRB at 410-502-2092 or jhmeirb@jhmi.edu.

What should you do if you have questions about the study, or are injured or ill as a result of being in this study?
Call the principal investigator, Dr. Kelly Dunn, Ph.D. at 410-550-2254. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

If you have an urgent medical problem or think you are injured or ill because of this study, call 911 or go to your local emergency department. You should also call Dr. Traci Speed, M.D. during regular office hours, or after hours/weekends at 410-870-7139.

17. Optional Study Components:

This part of the consent form is about optional component(s) of the study that you can choose to take part in or not. You can still take part in the main study even if you say "no" to this/these optional component(s).

Future Contact
We would like your permission for our research team to contact you in the future. Please note that your decision below does not prevent other researchers at Johns Hopkins from contacting you about other research.

Please sign and date your choice below:

YES ☐ _____ _____
Signature of Participant Date

NO ☐ _____ _____
Signature of Participant Date

18. What does your signature on this consent form mean?

Your signature on this form means that you have reviewed the information in this form, you have had a chance to ask questions, and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time

Signature of Person Obtaining Consent	(Print Name)	Date/Time

I have received the separate Insurance and Research Participant Financial Responsibility Information Sheet.

Signature of Participant, LAR or Parent/Guardian	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

DOCUMENTATION OF PHYSICIAN/MID-LEVEL PROVIDER CONSENT PROCESS

My signature below indicates that I have discussed the risks, benefits, and alternatives, answered any questions, and believe the participant is able to make an informed choice to join the study.

Signature of Physician/Mid-Level Provider	(Print Name)	Date/Time

Signature of Participant	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).